

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#4

Atty's Dkt: PEDERSEN10

In re Application of:  
Finn Skou PEDERSEN

Serial No. 10/514,626

IA Filing Date: May 15, 2003

For: A PURIFIED POLYPEPTIDE, ISOLATED NUCLEIC...

) Application Division

) ATTN: PCT

) Washington, D.C.

) Confirmation No. 7989

) Date: June 23, 2005

LATE SUBMISSION OF DECLARATION AND/OR TRANSLATION IN APPLICATION FILED UNDER 35 USC 371U.S. Patent and Trademark Office  
Customer Service Window  
Randolph Building, Mail Stop Missing Parts  
401 Dulany Street  
Alexandria, VA 22314

Sir:

The present communication is in response to the "NOTICE OF MISSING REQUIREMENTS UNDER 35 USC 371..." dated May 18, 2005. Attached hereto is/are:

- [XX] An executed oath or declaration in compliance with 37 C.F.R. 1.63, identifying the present application by title and priority information.
- [XX] A Preliminary Amendment [XX] Fees are reduced due to elimination of claim multiple dependencies.
- [XX] Copy of the "Sequence Listing" in computer readable form (CRF) and statement that contents of the CRF are the same as the paper copy.
- [XX] An Information Disclosure Statement with 08A- 1449 and 3 references.
- [XX] Additional fees as calculated below:

[ ] Basic fee		
Surcharge of \$130.00 for furnishing the oath or declaration later than [ ] 20 [XX] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$130.00
Number of each additional 50 pages or fraction thereof (round up to a whole number)	RATE	
	X \$250.00	
Number of Claims Previously Paid For	Number of Extra Claims	Rate
31 - 20 =	11	X \$ 50.00
2 - 3 =	0	X \$200.00
Multiple Dependent Claims (if applicable)	+ \$360.00	\$
TOTAL OF ABOVE CALCULATIONS		\$680.00
Reduction of 1/2 for filing by small entity, if applicable. Applicant claims small entity status. See 37 CFR 1.27.		<\$340.00>
SUBTOTAL		\$340.00
Processing fee of \$130.00 for late furnishing of the English translation.		\$
TOTAL NATIONAL FEE		\$340.00

- [ ] It is hereby petitioned for an extension of time in accordance with 37 C.F.R. 1.136(a). The appropriate fee required by 37 C.F.R. 1.17 is calculated as shown below:

Small Entity		
Response Filed Within		
[ ] First	-	\$ 60.00
[ ] Second	-	\$ 225.00
[ ] Third	-	\$ 510.00
[ ] Fourth	-	\$ 795.00
[ ] Fifth	-	\$1,080.00
month after time period set		

Other Than Small Entity		
Response Filed Within		
[ ] First	-	\$ 120.00
[ ] Second	-	\$ 450.00
[ ] Third	-	\$1,020.00
[ ] Fourth	-	\$1,590.00
[ ] Fifth	-	\$2,160.00
month after time period set		

[XX] Total fees enclosed: \$ 340.00

[XX] Credit Card Payment Form, PTO-2038, authorizing payment the amount of \$ 340.00 is enclosed to cover the above fees.

[XX] Conditional Petition for Extension of Time:

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR 1.16 and all patent processing fees under 37 CFR 1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR 1.18.

06/28/2005 MKAYPAGH 00000034 10514626

01 FC:2615  
02 FC:2617275.00 OP  
65.00 OPBROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

By:

Iver P. Cooper  
Registration No. 28,005

IPC:ses

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## UNITED STATES PATENT AND TRADEMARK OFFICE

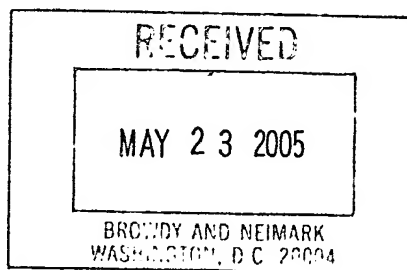
**Rec'd PCT/PTO 23 JUN 2005**

 UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/514,626	FIRST NAMED APPLICANT Finn Skou Pedersen	ATTY. DOCKET NO. PEDERSEN10
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INTERNATIONAL APPLICATION NO. PCT/DK03/00326
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IA. FILING DATE 05/15/2003	PRIORITY DATE 05/17/2002
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 1444  
 BROWDY AND NEIMARK, P.L.L.C.  
 624 NINTH STREET, NW  
 SUITE 300  
 WASHINGTON, DC 20001-5303

 CONFIRMATION NO. 7989  
 371 FORMALITIES LETTER


\*OC000000016048663\*

Date Mailed: 05/18/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 11/17/2004
- Copy of the International Search Report filed on 11/17/2004
- Copy of IPE Report filed on 11/17/2004
- Copy of Annexes to the IPER filed on 11/17/2004
- Biochemical Sequence Listing filed on 11/17/2004
- Request for Immediate Examination filed on 11/17/2004
- U.S. Basic National Fees filed on 11/17/2004
- Priority Documents filed on 11/17/2004

*SEQ/MSD - 18JL2005*

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of **\$2010** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- **\$130** Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$2140 for a Large Entity:

- \$130 Late oath or declaration Surcharge.
- This application does not contain a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). Applicant must provide such statement. If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- Total additional claim fee(s) for this application is \$ 2010
  - \$600 for 3 independent claims over 3.
  - \$1050 for 21 total claims over 20.
  - \$360 for multiple dependent claim surcharge.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

BARBARA A CAMPBELL

Telephone: (703) 308-9140 EXT 217

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/514,626	PCT/DK03/00326	PEDERSEN10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#7

In re Application of:	)	Art Unit:
Finn Skou PEDERSEN	)	
	)	Examiner:
	)	
Appln. No.: 10/514,626	)	Washington, D.C.
	)	
IA Filed: May 15, 2003	)	June 23, 2005
	)	
For: A PURIFIED POLYPEPTIDE,	)	Docket No.: PEDERSEN10
ISOLATED NUCLEIC ACIDS	)	
ENCODING SAID POLYPEPTIDE...	)	Confirmation No.: 7989

RESPONSE TO "SEQUENCE LISTING" REQUIREMENT

U.S. Patent and Trademark Office  
 Customer Service Window  
 Randolph Building, Mail Stop Missing Parts  
 401 Dulany Street  
 Alexandria, VA 22314

Sir:

In response to the Notice to Comply, mailed May 18, 2005,  
 please amend the application as follows:

REMARKS

1. Applicants hereby submit the following:
  - [ ] a paper copy of a "Sequence Listing", complying with \$1.821(c), to be incorporated into the specification as directed above;
  - [ ] an amendment to the paper copy of the "Sequence Listing" submitted on , the amendment being in the form of substitute sheets;
  - [XX] the Sequence Listing in computer readable form, complying with \$1.821(e) and \$1.824, including, if an amendment to the paper copy is submitted, all previously submitted data with the amendment incorporated therein;

- [ ] a substitute computer readable form to replace one found to be damaged or unreadable.
- [ ] The computer readable form in this application no. 09/... is identical with that filed on .... [date sequence was filed] in application no. 09/ , filed [filing date]. In accordance with 37 C.F.R. §1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].

2. The description is in compliance with §1.821(d).

3. The undersigned attorney or agent hereby states as follows:

- (a) this submission does not include new matter [§1.821(g)];
- (b) the contents of the paper copy (as amended, if applicable) and the computer readable form of the Sequence Listing, are the same [§1.821(f) and §1.825(b)];
- (c) if the paper copy has been amended, the amendment is supported by the specification and does not include

new matter [§1.825(a)]; and

- (d) if the computer readable form submitted herewith is a substitute for a form found upon receipt by the PTO to be damaged or unreadable, that the substitute data is identical to that originally filed [§1.825(d)].

4. Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two

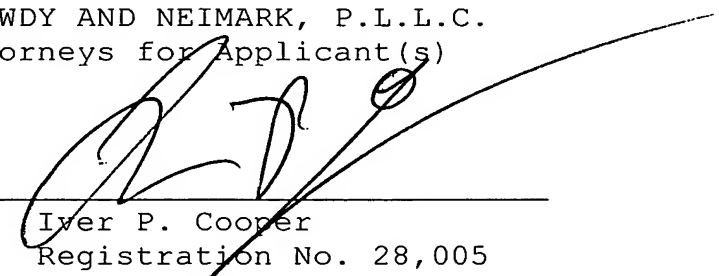
USSN - 10/514,626

or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The Examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

By:   
Iyer P. Cooper  
Registration No. 28,005

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